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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/578,861	04/10/2007	Timo Karmeniemi	BHD-2747-3	3338
23117 7590 11/21/2011 NIXON & VANDERHYE, PC 901 NORTH GLEBE ROAD, 11TH FLOOR ARLINGTON, VA 22203			EXAMINER KUMAR, KALYANAVENKA K	
			ART UNIT 3653	PAPER NUMBER
			MAIL DATE 11/21/2011	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/578,861	<b>Applicant(s)</b> KARMENIEMI ET AL.	
	<b>Examiner</b> KALYANA VENKATESHWAR KUMAR	<b>Art Unit</b> 3653	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 21 October 2011.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on \_\_\_\_; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 5) ☒ Claim(s) 10-23 is/are pending in the application.
- 5a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 6) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 7) ☒ Claim(s) 10-23 is/are rejected.
- 8) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 9) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 12) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 10-16 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Ekenburg et al (USP 5,567,326)** in view of **Hatch et al (USP 6,514,415 B2)**.

3. Regarding claims 10 and 16, Ekenburg discloses all the limitations of the apparatus and method including a device for separating magnetic particles from a liquid mixture thereof, the device comprising; a sample plate (40) defining a plurality of wells (24) for containing a liquid mixture comprised of a liquid and magnetic particles to be separated therefrom, and a vertically, reciprocally movable separating device, which comprises a reciprocally movable magnet head (34) a plurality of substantially aligned magnets (col. 8, lines 1-10; elements 28 as magnetically responsive metal elements and col. 8, lines 41-52 where the elements are employed in the magnetic separation) positioned relative to the sample plate so that each of the magnets is capable of being introduced into the liquid mixture contained in a respective one of the wells, wherein the magnetic particles are separated from the liquid, but Ekenburg does not disclose wherein at least some of the magnets are inversely oriented such that magnetic fields are fixed between adjacent ones of the magnets to thereby locally define collection of

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the magnetic particles at each magnet introduced into the liquid mixtures of the wells or that the magnets are permanent magnets. Hatch teaches that some magnets are inversely oriented such that magnetic fields are fixed between adjacent ones of the magnets to thereby locally define collection of the magnetic particles at each magnet introduced into the liquid mixtures of the wells for the purpose of facilitating consistent separation of particles across a container (col. 4, lines 45-50 and col. 6, lines 30-43 and Fig. 8c) and that the magnets can be permanent magnets (col. 4, lines 9-24).

Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Ekenburg, as taught by Hatch, for the purpose of facilitating consistent separation of particles across a container.

4. Regarding claim 11, Ekenburg/Hatch discloses about half of the magnets are inversely oriented (see Fig. 5b).

5. Regarding claim 12, Ekenburg/Hatch discloses substantially every second magnet is inversely oriented (see Fig. 5b).

6. Regarding claim 13, Ekenburg/Hatch discloses magnets are disposed in several rows of several magnets (see Fig. 5b).

7. Regarding claim 14, Ekenburg/Hatch discloses the magnets are united to form one single piece (see Fig. 5b and 220).

8. Regarding claim 15, Ekenburg/Hatch discloses the magnets are permanent magnets whose length/diameter ratio is at least about 2:1 (see Fig. 5b).

9. Regarding claim 19, Ekenburg discloses the magnets are elongated, and wherein the apparatus comprises a support plate and wherein the magnets are joined to and extend outwardly from the support plate (see Fig. 2, elements 28 and 30).

10. Claims 17, 18, and 20-23 rejected under 35 U.S.C. 103(a) as being unpatentable over Ekenburg/Hatch in view of **Gombinsky et al (USP 6,409,925 B1)**.

11. Regarding claims 17, 20, and 22, Ekenburg/Hatch discloses all the limitations of the claims as shown in claims 10 and 16 above, but Ekenburg/Hatch does not disclose the separating device further comprises: a vertically movable casing which defines a plurality of casing wells for receiving a respective one of the magnets of the magnet head, wherein the casing wells are positioned relative to the sample plate wells of the sample plate such that each of the sample plate wells is capable of receiving a respective one of the casing wells, and wherein the magnetic particles of the liquid mixture in the sample wells adhere to a separating area of the casing wells in response to the casing wells and the magnets received therein being moved vertically as a unit into a receiving relationship within the sample wells. Gombinsky teaches that it is obvious to use a cover for a separating device that is reciprocally movable with the device in a sample such that after contact with the particles and the reaction mixture it can be replaced by a clean or sterile tip or cover, and; therefore, provides an easy and inexpensive sterilization of the device (col. 6, lines 35-42 and see Figs. 1B, 3A, and 3B). All the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their

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respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

12. Regarding claim 18, Ekenburg/Hatch discloses the casings are united to form one single piece (see Fig. 4 and col. 3, lines 44-53).

13. Regarding claims 21 and 23, Ekenburg discloses the magnet head comprises a support plate, wherein each of the magnets are joined to and extend outwardly from the support plate (see Fig. 2).

### ***Response to Arguments***

14. Applicant's arguments filed 10/21/2011 have been fully considered but they are not persuasive.

15. **Rejection under USC 103**

16. Regarding Applicant's argument," Ekenberg does not therefore suggest or contemplate the use of permanent magnetic pins. If different pins should have to have opposite magnetic fields, one would then have to use several external magnets instead of one as clearly taught by Ekenberg. Ekenberg's device with inverted magnets would simply be technically infeasible," and," Significantly, Hatch does not disclose why more consistent separation is achieved. However, when one studies in greater detail the disclosure of Hatch, it is apparent that there is always a border line of two opposing magnets below the side wall or bottom (Fig. 7b) of each well. Thus, Hatch exemplifies only those arrangements in which one magnet always covers a plurality of wells. Hatch also makes reference in claim 1 to "magnets [being] arranged in a plane proximate the

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container." This clearly means that in principle, the magnets can be placed alternately on a side of the container. Placing magnets on an inside of the container is thus specifically excluded. Moreover, placing the Hatch magnets physically into the vessels of the container could not be accomplished without separating the magnets one from another which is specifically contrary to the very teaching of Hatch. Hatch teaching is also contradictory to the presently claimed invention. As noted above, Hatch keeps the particles in the vessels by means of magnets placed under the vessels. Liquid handling is needed with the risk of vessel to vessel cross- contamination. In the presently claimed invention (and in Ekenberg) pins are introduced into the vessels and the particles removed with the help of the pins. No liquid handling is needed. These two principles cannot be combined in any reasonable way to achieve any reasonable technical result. As such, Hatch cannot be of any help in modifying the Ekenberg device," the Examiner disagrees. The Examiner asserts that Hatch shows a configuration that uses many alternating permanent magnets where each magnet would only line up with one well. The Hatch reference is used to show that it is obvious to use alternating permanent magnets in a separation process for the purpose of increasing consistency of separation of particles across the container (see Figs. 8 and col. 6, lines 30-43).

### ***Conclusion***

17. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

18. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kalyan Kumar whose telephone number is 571-272-8102. The examiner can normally be reached on Mon-Fri 7:00AM-3:30PM.

20. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Stefanos Karmis can be reached on 571-272-6744. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

21. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a



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USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Kalyan Kumar

Examiner

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/JOSEPH C RODRIGUEZ/

Primary Examiner, Art Unit 3653